REMARKS

STATUS OF THE APPLICATION AND CLAIMS

With entry of this amendment, Applicants request reconsideration and allowance of the pending claims.

The applicants respectfully wish to note that a proper restriction and election of Group II was made in its previous response on June 2, 2003, in accordance with the Office Action dated May 2, 2003. *See* Amendment, 06/02/03. Group II was described by the Office as "Claims 2-9, drawn to a method for staging embryos comprising providing at least one embryo, detecting expression and correlating expression, classified in class 435, subclass 6." Office Action, 05/02/03, p. 2.

While the Office states in its most recent Action, dated August 4, 2003, that "Applicant's election of Group II, claims 2-9, . . . is acknowledged," it appears, however, that only claims 2-6 were examined by the Office in error. *See* Office Action, 08/04/03. For example, both the form PTO-326 and the Detailed Action state that "Claim(s) 1 and 7-61 are withdrawn from consideration." *Id.* at 1-2. The detailed action further states that only "claims 2-6 . . . are examined on the merits." *Id.* at 2. Likewise, the summary sheet echoes this sentiment and states that claims 2-6 are rejected. *Id.* at 1. Accordingly, it is applicants' belief that claims 7 through 9 have been improperly withdrawn and thus, not considered on their merits. The applicants respectfully request that this error be corrected and claims 7, 8 and 9 be allowed.

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Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office rejected claim 6 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter the applicants regards as their invention. *Id.* at 2. Specifically, the term "under conditions of high stringency" is said to cause the claim to be vague and indefinite. *Id.*

The Applicants traverse this rejection. The specification states that "nucleic acid molecules within the scope of the invention include sequences that hybridize to sequences of SEQ ID NOS: 1-334 under hybridization and wash conditions of 5°, 10°, 15°, 20°, 25°, or 30° below the melting temperature of the DNA duplex of sequences of SEQ ID NOS: 1-334. . . ." Specification at 18-19, ¶ 47. Further, Applicants describe that "stringency conditions in nucleic acid hybridizations can be readily determined by those having ordinary skill in the art based on, for example, the length and composition of the nucleic acid. In one embodiment, moderate stringency is herein defined as a nucleic acid having 10, 11, 12, 13, 14, 15, 16, or 17, contiguous nucleotides identical to any of the sequences of SEQ ID NOS: 1-334, or a complement thereof. Similarly, high stringency is hereby defined as a nucleic acid having 18, 19, 20, 21, 22, or more contiguous identical nucleotides, or a longer nucleic acid having at least 80, 85, 90, 95, or 99 percent identity with any of the sequences of SEQ ID NOS: 1-334; for sequences of at least 50, 100, 150, 200, or 250 nucleotides, high stringency may comprise an overall identity of at least 60, 65, 70 or 75 percent." *Id.* at 20, ¶ 50.

In view of the above, Applicants respectfully assert that claim 6 particularly points out and distinctly claims the subject matter it regards as the invention. Accordingly, the rejection to claim 6 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

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Rejections Under 35 U.S.C. § 101

The Office rejected claims 2-6 as lacking patentable utility because they are unsupported by a specific, substantial, and credible utility, or in the alternative, a well-established utility. *See* Office Action, 08/04/03, at 4. Specifically, the Office states that "the critical limitation of claims 2-6 is the **method of using of the claimed polynucleotides** SEQ ID NO: 79 and 131" and that the claimed nucleic acid is not supported by a specific asserted utility because the disclosed uses . . . mentioned in the specification are generally applicable to many nucleic acids." *Id.* (emphasis added.) Additionally, the Office rejects claims 2-6 stating that the "claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter." *Id.*

The Applicants traverse this rejection and assert that contrary to the Office's conclusion, a specific utility for claims 2-9 is described wholly within the specification. For instance, even though the Office characterized the "critical limitation" of the claims as a "method of using the claimed polynucleotides," an accurate limitation is of course defined by the claims themselves. Independent claim 2 states:

> A method of staging embryos comprising:
> a) providing at least one embryo;
> b) detecting the expression in the embryo of at least one RNA transcript of Table I; and
> c) correlating the expression of said transcript to one or more embryonic stages.

Thus, a utility of the invention is its ability to accurately stage embryos by the expression pattern of certain transcripts. This is supported throughout the specification. For instance, the invention, therefore, is "useful in the design, selection, and cultivation

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of improved crops, specifically including coniferous trees, which provide raw materials for paper and wood products." Specification at 2, ¶ 2.

The current approach used in the art for precise developmental staging of an embryo requires a practiced, physical familiarity with the morphological appearance of embryos at different stages. *See* Pullman and Webb, Tappi R&D Division 1994 Biological Sciences Symposium, pp. 31-34. In other words, the current staging approach is a visual process that is both tedious and prone to error. Furthermore, the traditional morphological staging method provides only a crude indication of the underlying biochemical condition of an embryo thereby making it insufficient for refining culture conditions or selecting potentially advantageous embryo clones for further development. Specification at 9, ¶ 18. The present invention, to the contrary, allows definitive staging beyond that practiced in the art. The specification teaches an approach that provides a detailed analysis of the biochemical state and potential fitness of the of an embryo by comparison to a developed set of data, which can be practiced without vast experience in visual staging. *Id*; *see also* Specification at 128, Table II.

Consequently, since both environmental requirements and responsiveness of a developing embryo change as the embryo passes various developmental milestones, accurate and timely knowledge of the developmental stage of an embryonic culture would allow the skilled practitioner to beneficially adjust the growth media components and other environmental factors to achieve optimal embryo survival, growth and maturation. Specification at 8, ¶ 16. Applicants demonstrate the invention achieves this utility.

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Applicants assert that this utility is specific, substantial, and credible utility that meets the Office's requirements under the Revised Interim Utility Guidelines. 64 Fed. Reg. 71440, 71441 (1999). Accordingly, the rejection to pending claims 2-6 under 35 U.S.C. § 101, should be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Office asserted that one skilled in the art would not know how to use the claimed invention because it is not supported by a specific, substantial and credible utility. The Office, therefore, rejected claims 2-6 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed sequence. As explained above, since the claimed invention has a specific, substantial and credible utility, this enablement rejection cannot be sustained. Applicants respectfully request that the rejection be withdrawn.

Moreover, the Office states that "[f]or a sequence putatively assigned a biological function, even if correct, [it] does not appear to be defined as to what use it is to be applied to. The significance of the sequence is undefined, further rendering it indiscernible how someone of skill in the art would use such an entity." Office Action, 08/04/03, at 6. Applicants respectfully suggest that given the language of independent Claim 2, and the stated utility of the invention for determining a specific biological stage of an embryo, one skilled in the art would sufficiently understand how to use the

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particular sequences listed in Table I of the present specification. The Applicants respectfully request this rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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